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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/814,696	03/30/2004	Christopher J. Ryan	8932-881-999	7229

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222 EAST 41ST STREET
NEW YORK, NY 10017-6702

EXAMINER

SHAFFER, RICHARD R

ART UNIT	PAPER NUMBER
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3733

DATE MAILED: 03/20/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/814,696	Applicant(s) RYAN, CHRISTOPHER J.	
	Examiner Richard R. Shaffer	Art Unit 3733	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 February 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-62 is/are pending in the application.
- 4a) Of the above claim(s) 56-62 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-55 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 30 March 2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>7/7/2004</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Applicant's election of Group I (Claims 1-55) in the reply filed on February 21st, 2006 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 56-62 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on February 21st, 2006.

Drawings

The drawings are objected to because they do not clearly depict the structure of the invention. Solid black regions and small details for critical components cause confusion and unclear understanding of the invention. It is recommended to enlarge the drawings as well as clearly show all structure included, as well as avoiding handwritten reference characters. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered

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and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC §. 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-55 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 1 and 29 applicant states the device has a proximal and distal end for the drill bit, housing, and depth stops. This causes the claim to be indefinite, especially in dependent claims because it is unclear which proximal or distal end applicant is referring to.

Claim 1 recites the limitation "the second end" in line 5. There is insufficient antecedent basis for this limitation in the claim.

All dependent claims have been rejected for being dependent upon an indefinite claim.

Claim Rejections - 35 USC § 101

Claims 1-55 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claims 1 and 29 state that the housing is "associated with a bone portion." One cannot positively recite the human body as a claimed limitation. It is recommended applicant modifies the language to indicate that the device is capable of, such as adapted for association with a bone portion.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-5, 7-11, 29-33, 36-39, and 41-45 are rejected under 35 U.S.C. 102(b) as being anticipated by Lightman, et al (US Patent 5,810,828).

Lightman, et al disclose a tool comprising: a drill bit (3) configured to connect to a driving attachment (25) and having a cutting surface; a proximal (9) and distal (1) housing with a bore to slidably receive the drill bit, the distal end of the housing configured to engage a bone portion or fastener hole in a bone plate (Column 1, Lines 1-55 and Column 9, Lines 10-11) to fix the trajectory of the drill bit; the drill bit (3) is axially positionable with respect to the housing (1, 9) having an extended position (**Figure 1b**) in which the distal end (22) of the drill bit extends distally beyond the housing distal end (26) and a retracted position (**Figure 1a**) in which the distal end of the drill bit does not extend distally beyond the housing distal end (26); a spring (10)

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associated with the drill bit on the internal surface and the housing on its external surface is operable to bias the drill into the retracted position; the drill bit further comprising an axial engagement portion (the portion adapted for direct engagement with **25**) which indirectly engages with a corresponding housing engagement portion (**23**) to prevent the drill bit from moving axially past the proximal end of the housing; the proximal end of the distal housing has recesses and protrusions (**30**) which engage with recess (**54**) through retainer (**6**, which also allows for the two components to be disassembled) at the distal end of the proximal housing to rotationally fix the two housing portions; the proximal end (near **40**) of the proximal housing has an increased diameter and is capable of being gripped by a user; an adjustable stop assembly (**5, 12**) also having a bore configured to receive the drill bit (**3**); and the depth stop having a portion (**15**) adapted to engage a proximal stop surface (**52**) of the proximal housing portion thereby selectively locking the drill bit to the bore such that when the drill bit is locked to the adjustable depth stop, the proximal end of the housing is located at a first axial distance from the distal end of the adjustable depth stop, the first axial distance proportional to a maximum drilling depth into a bone portion.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 6, 13-17, and 34-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lightman, et al in view of Michelson (US Patent 6,193,721).

Lightman, et al discloses all of the claimed limitations except the distal housing comprises threads to engage with the threads of a fastener hole in a spinal fixation plate. Michelson teaches (Column 23, Line 55 through Column 24, Line 20) that threading the distal end of a guide device assures a stable fit. This would minimize the chance of accidentally injuring surrounding tissue. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Lightman, et al to include threads at the distal end of the housing to provide for a stable fit with the bone fixation plate thereby minimizing the chance of surrounding tissue damage.

Allowable Subject Matter

Claims 12, 18-28, 40, and 46-55 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 101 and 35 U.S.C. 112, 2nd paragraph, as set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Richard R. Shaffer whose telephone number is 571-272-8683. The examiner can normally be reached on Monday-Friday during (7am-5pm).

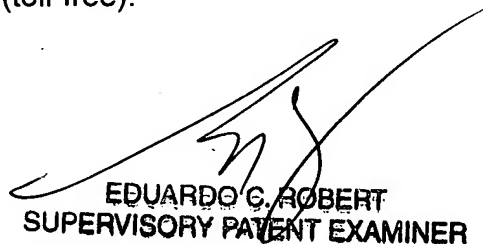
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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Richard Shaffer
March 11th, 2006



EDUARDO G. ROBERT
SUPERVISORY PATENT EXAMINER